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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,187	06/20/2003	Timothy J. O'Brien	D6064CIP/D2	8237

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/600,187

Applicant(s)

O'BRIEN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 18-31 and 36-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment and Arguments

1. Claims 1-52 are pending.

Claims 1-11, 18-31 and 36-52, drawn to non-elected inventions are withdrawn from examination.

Claims 12, 16 and 34 have been amended.

Claims 12-17 and 32-35 will be examined to the extent they read on detecting a nucleic acid.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection

Claim Objections

3. The objection of claim 34 is withdrawn to because assays that are not applicable to the elected and examined Group and the incorrect word, "ELIZA" on line 3 have been deleted from the claim.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

4. The rejection of claims 12-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in light of the amendments to claims 12 and 16.

Maintained Rejections

Claim Rejections - 35 USC § 112

5. The rejection of claims 32-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Applicants assert these aforementioned claims read on the TADG-15 nucleic acid outlined in claims 12-17 and consequently, the instant rejection should be withdrawn. This point of view, as well as other accompanying arguments have has been carefully considered, but found unpersuasive.

While claim 32 and claims 12-17 may share essential subject matter such as a method of detecting TADG-15 in a sample, claims 12-17 clearly express TADG-15 mRNA is detected with a probe specific for TADG-15 encoded by SEQ ID NO: 1. Claims 32-35 do not clearly identify the TADG-15. Applicants' claims 32-35 continue to broadly claim a method of detecting TADG-15, which has not been identified or characterized. Applicants are not entitled, nor is the specification enabled for the use of all TADG-15 nucleic acid or protein and probes specific for an undefined and uncharacterized TADG-15. Applicants are not permitted to claim all tumor antigen

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derived gene-15 molecules that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue. There is no disclosure, beyond the mention of SEQ ID NO: 1 as a TADG-15 nucleic acid made in the specification, page 14.

Applicants' claims including the recitation "tumor antigen derived gene-15 (TADG-15)" encompass variants, mutants and proteins from not only humans, but other animals. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the claims.

Applicants can obviate the instant rejection by amending the claims to reflect that the TADG-15 mRNA of the claims reads specifically on SEQ ID NO: 1.

6. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicants argue the means of detecting the label is implemented with reagents or machines. And detection of the label is providing the detection of the target nucleic acid, TADG-15, see Remarks, page 15 and 1st full paragraph. These points of view have been carefully considered, but found unpersuasive.

It is incumbent upon the Examiner to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. This is to be done when the claimed invention is defined using means plus function language, MPEP 2106. However, the

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instant claim does not provide limitations that define the means, nor correlating the detection of the label with any endpoint. There is no function language in regards to means for detecting the label. The limitations Applicants' discuss on page 15 of the Remarks submitted December 1, 2006 are remiss in the claims and seemingly the specification, as well. The "means" is not defined by the claims, therefore do not define the terms, nor limit the scope. The rejection is maintained for the reasons presented herein and of record. Furthermore, the "means for detecting said label" is not commensurate with the endpoint of the method comprised in the kit. It seems that the label with which to label said probe and means cited in the claim are two separate articles that should be made clear in the claims.

Double Patenting

7. The rejection of claims 12-17 and 32-35 under the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,972,616 (issued October 26, 1999) is maintained.

Applicants assert claims 12 and 16 have been amended to include SEQ ID NO: 1 and the claims of the instant application and those of the patent are distinct, see Remarks, page 16, 1st paragraph. Applicants aver claim 11 of the patent reads on a method of detecting expression of the entire TADG-15 protein, while the claims of the instant invention read on a method of detecting the transcript of TADG-15 encoded by SEQ ID. NO: 1. These arguments have been carefully considered, but found unpersuasive.

The claims of the instant application and claim 11 of the patent clearly share the same active steps and endpoint of detecting mRNA bound by a probe with hybridization. Applicants' assertion that the patent's claim reads on detection of the entire TADG-15 protein is not precise. The active steps are the same and hence the rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
09 February 2007